Rule 7. Sealed Radioactive Sources in the Healing Arts

410 IAC 5-7-1 Scope of rule

Sec. 1. The provisions of 410 IAC 5-7 apply to all licensees or registrants who use sealed sources in the healing arts and are in addition to, and not in substitution for, other applicable provisions of 410 IAC 5.

410 IAC 5-7-1.1 Definitions

Sec. 1.1. As used in 410 IAC 5-7, the following definitions apply:

"Brachytherapy" means a method of radiation therapy in which an encapsulated source or group of sources is utilized to deliver beta or gamma radiation at a distance of up to a few centimeters, by surface, intracavitary, or interstitial application.

"Teletherapy" means therapeutic irradiation in which the source of radiation is at a distance from the body.

410 IAC 5-7-2 Interstitial, intracavitary, and superficial applications

Sec. 2. (a) Accountability, Storage and Transit.

(1) Except as otherwise specifically authorized by the board, each licensee shall provide accountability of sealed sources and shall keep a record of the issue and return of all sealed sources to their place of storage.

(2) Each licensee or registrant shall conduct a physical inventory at intervals not to exceed 6 months to account for all sources and devices received and possessed. Records of the inventories shall be maintained for inspection by the board and shall include the quantities and kinds of radioactive material, location of sources and devices, and the date of the inventory.[1]/

[1]/ The U.S. Nuclear Regulatory Commission requires these inventories to be done on a quarterly basis.

(3) Each licensee shall follow the radiation safety and handling instructions approved by the board, the U.S. Nuclear Regulatory Commission, an agreement state, or a licensing state and furnished by the manufacturer on the label attached to the source, device, or permanent container thereof, or in the leaflet or brochure which accompanies the source or device, and maintain such instruction in a legible and conveniently available form.

(4) Each licensee or registrant shall assure that needles or standard medical applicator cells containing cobalt-60 as wire, radium-226, or cesium-137 are not opened while in the licensee's or registrant's possession unless specifically authorized by a license or permit issued by the board.

(b) Testing Sealed Sources for Leakage and Contamination.

(1) All sealed sources, containing more than 100 microcuries of radioactive material with a half-life greater than 30 days, or 10 microcuries of radium-226, shall be tested for leakage and/or contamination at intervals not to exceed 6 months or at such other intervals as are approved by the board, the U.S. Nuclear Regulatory Commission, an agreement state or a licensing state and described by the manufacturer on the label attached to the source, device or permanent container thereof, or in the leaflet or brochure which accompanies the source or device. Each source or device shall be so tested prior to its first use unless the supplier furnishes a certificate that the source or device has been so tested within 6 months prior to the transfer.

(2) Leak tests shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample or, in the case of radium, the escape of radon at the rate of 0.001 microcurie per 24 hours. The test sample shall be taken from the source or from the surfaces of the device in which the source is permanently or semipermanently mounted or stored on which one might expect contamination to accumulate. Any test conducted pursuant to 410 IAC 5-7-2(b)(1) which reveals the presence of 0.005 microcurie or more of removable contamination or, in the case of radium, the escape of radon at the rate of 0.001 microcurie or more per 24 hours shall be considered evidence that the sealed source is leaking. The licensee shall immediately withdraw the source from use and shall cause it to be decontaminated and repaired or to be disposed of in accordance with applicable provisions of 410 IAC 5-4. A report shall be filed with the board within 5 days of the source withdrawal describing the equipment involved, the test results, and the corrective action taken.

(3) Leak test results shall be recorded in units of microcuries and maintained for inspection by the board.

(c) Radiation Surveys.

(1) The maximum radiation level at a distance of one meter from the patient in whom brachytherapy sources have been inserted shall be determined by measurement or calculation. This radiation level shall be entered on the patient's chart and other signs as required under 410 IAC 5-7-2(d).

(2) The radiation levels in the patient's room and the surrounding area shall be determined, recorded, and maintained for inspection by the board.

(3) The licensee or registrant shall assure that patients treated with the cobalt-60, cesium-137, iridium-192 or radium-226 implants remain hospitalized until a source count and radiation survey of the patient confirm that all implants have been

removed.

(d) Signs and Records.

(1) In addition to the requirements of 410 IAC 5-4-11, the bed, cubicle, or room of the hospital brachytherapy patient shall be marked with a sign indicating the presence of brachytherapy sources. This sign shall incorporate the radiation symbol and specify the radionuclide, the activity, date, and the individual(s) to contact for radiation safety instructions. The sign is not required provided the exception in 410 IAC 5-4-12(b) is met.

(2) The following information shall be included in the patient's chart:

(i) The radionuclide administered, number of sources, activity in millicuries and time and date of administration;

(ii) The exposure rate at 1 meter, the time the determination was made, and the name of the individual who made the determination;

(iii) The radiation symbol; and

(iv) The precautionary instructions necessary to assure that the exposure of individuals does not exceed that permitted under 410 IAC 5-4-2.

410 IAC 5-7-3 Teletherapy

Sec. 3. (a) Equipment.

(1) The housing shall be so constructed that, at 1 meter from the source, the maximum exposure rate does not exceed 10 milliroentgens per hour when the beam control mechanism is in the "off" position. The average exposure rate measured at a representative number of points about the housing, each 1 meter from the source, shall not exceed 2 milliroentgens per hour.

(2) For teletherapy equipment installed after the effective date of 410 IAC 5, the leakage radiation measured at 1 meter from the source when the beam control mechanism is in the "on" position shall not exceed 0.1 percent of the useful beam exposure rate.

(3) Adjustable or removable beam-defining diaphragms shall allow transmission of not more than 5 percent of the useful beam.

(4) The beam control mechanism shall be of a positive design capable of acting in any orientation of the housing for which it is designed to be used. In addition to an automatic closing device, the mechanism shall be designed so that it can be manually returned to the "off" position with a minimum risk of exposure.

(5) The closing device shall be so designed as to return automatically to the "off" position in the event of any breakdown or interruption of the activating force and shall stay in the "off" position until activated from the control panel.

(6) When any door to the treatment room is opened, the beam control mechanism shall automatically and rapidly restore the unit to the "off" position and cause it to remain there until the unit is reactivated from the control panel.

(7) There shall be at the housing and at the control panel a warning device that plainly indicates whether the beam is "on" or "off."

(8) The equipment shall be provided with a locking device to prevent unauthorized use.

(9) The control panel shall be provided with a timer that automatically terminates the exposure after a preset time.

(10) Provision shall be made to permit continuous observation of patients during irradiation.

(b) Operation. No individual shall be in the treatment room during irradiation unless that individual is the patient. Mechanical restraining or supporting devices shall be used for positioning the patient, if necessary.

(c) Testing for Leakage and Contamination. Teletherapy sources shall be tested for leakage and contamination in accordance with the procedures described in 410 IAC 5-7-2(b). Tests of leakage may be made by wiping accessible surfaces of the housing port or collimator while the source is in the "off" position and measuring these wipes for transferred contamination.

(d) Calibration and Physical Decay Determinations.

(1) Calibration measurements shall be performed by a qualified radiation therapy physicist on each teletherapy unit:

(i) Prior to the first use of the unit for treating humans;

(ii) Prior to treating humans;

(A) Whenever spot-check measurements indicate that the output value differs by more than 5 percent from the value obtained at the last calibration corrected mathematically for physical decay;

(B) Following replacement of the radiation source or following reinstallation of the teletherapy unit in a new location; and

(C) Following any repair of the teletherapy unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and

(iii) At intervals not exceeding 1 year.

(2) Calibration measurement shall include determination of:

(i) The exposure rate or dose rate to an accuracy within 3 percent for the range of field sizes and for the range of distances or for the axis distance, used in radiation therapy;

(ii) The congruence between the radiation field and the field indicated by the light beam localizing device;

(iii) The uniformity of the radiation field and its dependence upon the orientation of the useful beam;

(iv) Timer accuracy; and

(v) The accuracy of all distance measuring devices used for treating humans.

(3) The exposure rate or dose rate values shall be corrected mathematically for physical decay at intervals not exceeding 1 month.

(4) Calibration measurements and physical decay corrections shall be performed by a qualified radiation therapy physicist in accordance with 410 IAC 5-7-3(g).

(e) Spot-Check Measurements

(1) Spot-check measurements shall be performed on each teletherapy unit at intervals not exceeding 1 month.

(2) Spot-check measurements shall include determination of:

(i) Timer accuracy;

(ii) The congruence between the radiation field and the field indicated by the light beam localizing device;

(iii) The accuracy of all distance measuring devices used for treating humans;

(iv) The exposure rate, dose rate or a quantity related in a known manner to these rates for one typical set of operating conditions; and

(v) The difference between the measurements made in 410 IAC 5-7-3(e)(2)(iv) and the anticipated output expressed as a percentage of the anticipated output. The anticipated output is the value obtained at the last calibration corrected mathematically for physical decay.

(3) Spot-check measurements shall be performed in accordance with procedures established by a qualified radiation therapy physicist in accordance with 410 IAC 5-7-3(g)(1). A qualified radiation therapy physicist need not actually perform the spot-check measurements. If a qualified radiation therapy physicist does not perform the spot-check measurements, the results of the spot-check measurements shall be reviewed by a qualified radiation therapy physicist within 15 days.

(f) Dosimetry System Calibration

(1) Calibration measurements shall be performed using a dosimetry system that has been calibrated by the National Bureau of Standards or by a Regional Calibration Laboratory accredited by the American Association of Physicists of Medicine. The dosimetry system shall have been calibrated within the previous 2 years and after any servicing that may have affected system calibration.

(2) Spot-check measurements shall be performed using a dosimetry system that has been calibrated in accordance with 410 IAC 5-7-3(f)(1). Alternatively, a dosimetry system used solely for spot-check measurements may be calibrated by direct intercomparison with a system that has been calibrated in accordance with 410 IAC 5-7-3(f)(1). This alternative calibration method shall have been performed within the previous 1 year and after each servicing that may have affected system calibration. Dosimetry systems calibrated by the alternative method shall not be used for teletherapy calibration measurements.

(g) Records. The licensee or registrant shall maintain, for inspection by the board, records of the measurements, tests, corrective actions, and instrument calibrations.

(1) Records of teletherapy calibration measurements and calibration of the instruments used to make these measurements shall be preserved for 5 years after completion of the teletherapy calibration.

(2) Records of spot-check measurements and corrective actions and calibration of instruments used to make spot-check measurements shall be preserved for 2 years after completion of the spot-check measurements and corrective actions.